



3. The Agency administers the State of Hawaii's Certificate Program, pursuant to Chapter 323D, Hawaii Revised Statutes (HRS), and Title 11, Chapter 186, Hawaii Administrative Rules (HAR).

4. On January 27, 2003, the applicant filed with the Agency a Certificate of Need application for the establishment of a cardiac catheterization laboratory at 91-2141 Fort Weaver Road, Ewa Beach, HI at a capital cost of \$1,800,000. (the "Proposal"). On April 16, 2003 and April 30, 2003, the applicant submitted additional information. On May 1, 2003 the application was determined to be complete. For administrative purposes, the Agency designated the application as Cert. #03-02.

5. The period for Agency review of the application commenced on May 3, 2003, the date on which the review schedule for the application appeared in the newspaper of general circulation pursuant to Section 11-186-39 HAR.

6. The application was reviewed by the Oahuwide Certificate of Need Review Committee at a public meeting on May 9, 2003. The Committee recommended approval of this application by a vote of 3 in favor and 2 opposed.

7. The application was reviewed by the Certificate of Need Review Panel at a public meeting on May 16, 2003. The Panel unanimously recommended approval of the Proposal by a vote of 6 in favor and none opposed.

8. The application was reviewed by the Statewide Health Coordinating Council at a public meeting on May 22, 2003. The Council unanimously recommended approval of the Proposal by a vote of 14 in favor and none opposed.

9. This application was reviewed in accordance with Section 11-186-15, HAR.

10. Pursuant to Section 323D-43(b), HRS:

"(b) No Certificate shall be issued unless the Agency has determined that:

- (1) There is a public need for the facility or service; and
- (2) The cost of the facility or service will not be unreasonable in the light of the benefits it will provide and its impact on health care costs."

11. Burden of proof. Section 11-186-42, HAR, provides:

"The applicant for a certificate of need or for an exemption from certificate of need requirements shall have the burden of proof, including the burden of producing evidence and the burden of persuasion. The degree or quantum of proof shall be a preponderance of the evidence."

II

**FINDINGS OF FACT**

**A. REGARDING THE RELATION OF THE PROPOSAL TO THE STATE HEALTH SERVICES AND FACILITIES PLAN (HAWAII HEALTH PERFORMANCE PLAN) OR "H2P2"**

Vision and Guiding Principles (Chapter II)

12. The applicant states that the Proposal responds to the H2P2 objective of the early detection and diagnosis of treatable diseases by providing "early detection and care for cardiac patients."

13. The applicant states that the Proposal addresses the basic principals for a health care delivery system by providing "tertiary cardiac care in the diagnosis, detection and intervention of coronary artery disease." The applicant further states that it will coordinate these services with other tertiary services offered at St. Francis Medical Center-West (SFMC-W), the Oahu-wide EMS system and St. Francis Medical Center-Liliha.

14. With respect to the H2P2 critical element of access to care, the applicant states that the Proposal allows the applicant "to provide acute cardiac services within the 'golden hour' (within 60 to 90 minutes of the heart attack) to a wide surrounding area."

15. With respect to the H2P2 critical element of cost-effectiveness, the applicant states that "there is collated research reported from the ACC (American College of Cardiology) demonstrating the cost-effectiveness of this type of early intervention."

Statewide and Regional Priorities (Chapter III)

16. The applicant states that the Proposal addresses the West Oahu Subarea Health Planning Council's priority H2P2 chapter ("a. Priority Chapters. Diabetes and other Chronic Disabling Conditions; Heart Disease and Stroke") by strengthening the ability of SFMC-W to diagnose and treat heart disease.

17. The applicant also states that the Proposal addresses another West Oahu Subarea Health Planning Council priority ("b. Existing services. Should be strengthened in all areas") by collaborating with the State EMS system to provide

prompt care to cardiac patients living within the 'golden hour' of the hospital.

Diseases and Conditions (Chapters IV-XI)

18. The applicant states at Page A-16 of its application:

"Chapter VII Heart Disease and Stroke states '... it has been shown that aggressive management of risk factors, through lifestyle modification and medical intervention, can forestall further complications in patients diagnosed with CHD and stroke.' (H2P2 page VII-2) A cath lab at SFMC-W will provide the diagnosis and sometimes intervention itself for the aggressive management to forestall complications referred to above."

19. In a memorandum dated May 15, 2003, Debbie Morikawa, Chair, Oahuwide Certificate of Need Review Committee forwarded the Committee's recommendation for approval of this application. The recommendation states in pertinent part:

"The application is consistent with the provisions of H2P2, including the H2P2 statewide objectives of early detection and diagnosis of treatable diseases and reducing morbidity and pain through timely and appropriate treatment. The proposal will also help achieve the West Oahu regional priority of providing a seamless continuum of comprehensive care delivery."

20. The Agency finds that this criterion has been met.

**B. REGARDING NEED AND ACCESSIBILITY CRITERIA**

21. The applicant states that the Proposal will be accessible to all persons, in particular, low-income persons, racial and ethnic minorities, women, people with disabilities, other underserved groups, and the elderly.

22. At page 6 of the application, the applicant states:

"There are two general types of cardiac catheterization services. Diagnostic, where early signs of heart attack or heart disease have been detected and the cardiac cath is used to identify blockages that can lead to heart attacks; and interventional, when a heart attack is imminent or has already happened, balloons and other devices are used to open the blocked arteries."

23. The applicant states that the minimum utilization thresholds for cardiac catheterization outlined in H2P2 are met in all instances except Castle and Kapiolani at Pali Momi. The applicant further states that "both of these facilities have cardiac catheterization labs and machines that are by design and CON application, used solely for diagnostic purposes. They do not do invasive procedures."

24. The applicant states that a professional practice guideline regarding cardiac catheterization interventions was recently released jointly by the American College of Cardiology (ACC) and the American Heart Association (AHA). At page B-3, the applicant states:

"The 'golden hour' is the time from the start of symptoms of a heart attack to initiation of cath lab procedures. This early intervention is deemed so critical that a professional practice guideline was released jointly by the American College of Cardiology (ACC) and the American Heart Association (AHA) stating that if definitive treatment (balloon dilatation) can be initiated within the 'golden hour' it should be performed to reduce chronic debilitating outcomes. Further this optimal cardiac intervention could and should be performed in labs such as this project planned at SFMC-W, even without open heart surgery, where cath lab balloon procedures are available within the 'golden hour', and that this would reduce chronic heart disease over medical therapy (JACC vol. 37, no.8, June 2001). Previously The ACC had recommended that intervention only be carried out in cardiac cath labs with heart surgery capability. By June 2001 there was enough compelling evidence to show that lives would be saved and chronic disease reduced, safely, by immediate intervention, with balloons and other devices, whether or not heart surgery is performed at the hospital. The ACC then changed its recommendation for interventions in cardiac cath labs such as this proposed project."

25. The applicant states that neighborhoods within the golden hour of SFMC-W are Waipahu, Ewa, Waianae Coast, Mililani/Waipio, Wahiawa, North Shore, Makakilo/Kapolei, Mililani Mauka and a portion of Koolauloa. The applicant further states that there are 283,496 residents living in these neighborhoods and that a portion of this target population is Native Hawaiian and at greater risk than the general population.

26. The applicant states that the population within the "golden hour" of SFMC-W grew at a rate of 135% over the last ten years and near double digit growth is expected to continue.

27. In a memorandum dated May 21, 2003, Winifred Odo, Chair, Certificate of Need Review Panel forwarded the Committee's recommendation for approval of this application. The recommendation states in pertinent part:

"The proposal will enable the applicant to provide "golden hour" coverage for heart attacks to a large portion of the population of Oahu i.e. central, west and north Oahu."

28. The Agency finds that the cardiac catheterization labs at Pali Momi and Castle Medical Center cannot be utilized to address the interventional cardiac care needs of patients within the golden hour of the applicant's proposed service.

29. The Agency finds that the need and access criteria have been met.

#### C. REGARDING QUALITY AND LICENSURE CRITERIA

30. The applicant states that in June 2001, the American Heart Association and the American College of Cardiology concluded that "there are significantly improved outcomes and reduction of chronic heart disease, when cath lab intervention occurs within 60 to 90 minutes ('Golden Hour') of the heart attack." The applicant states that the Proposal will improve the quality of care for cardiac patients who experience heart attacks at SFMC-W which is the State of Hawaii's second busiest emergency department.

31. The applicant states that all staff "...will be nationally certified and or licensed as appropriate to the job requirements. A registered nurse will be in attendance during all procedures to monitor the patient and provide for individual patient care."

32. The applicant states that all staff types are required to attend continuing education to maintain competencies in the specialty areas.

33. The applicant states that its "sister cardiac cath lab to this project, Island Cardiac Centers at SFMC-Liliha, will provide start-up staffing, on call response and training of initial staff for the start up. Initial management of this cath lab will also come from the Liliha cath lab. The Liliha cath lab has an existing training program with qualified, personnel in queue to be available at start up."

34. The applicant states that a transfer agreement is in place with SFMC-Liliha "to provide care required beyond the current scope of the cath lab or SFMC-W, such as open heart surgery."

35. In her memorandum dated May 21, 2003, Winifred Odo, Chair, Certificate of Need Review Panel states in pertinent part: "Quality cardiac care is well

established at St. Francis-Liliha. This proposal will utilize expertise and personnel from that hospital."

36. The applicant states that St. Francis Medical Centers at both West and Liliha are accredited by JCAHO and that its proposed service will also apply for JCAHO accreditation.

37. The applicant states that the proposed service "...will be certified as an ambulatory surgery center performing cardiac catheterization by the Centers for Medicare/Medicaid Services (CMS)."

38. The Agency finds that quality and licensure criteria have been met.

#### D. REGARDING THE COST AND FINANCIAL CRITERIA

39. The applicant projects that the total capital cost of the Proposal will be \$1,800,000 and that \$1,450,000 will be financed by new debt with the remainder coming from the cash contributions of National Medical Development, SFMC-W, Cardiovascular Associates and Island Cardiac Centers.

40. The applicant projects that for Year 1 of the proposal, net revenues will be \$1,797,000 and net income will be \$29,814. The applicant projects that for Year 3 of the proposal, net revenues will be \$3,000,000 and net income will be \$587,688.

41. The applicant states that initial operating expenses are covered by a line of credit established through Cardiovascular Associates L.L.C.

42. With respect to the effect that the Proposal will have on health care costs, the applicant states at page D-7 of its application:

"There is collated research reported from the ACC demonstrating the cost effectiveness of this type of early intervention in some types of acute heart attacks. In June 2001, the American Heart Association (AHA) and the American College of Cardiology (ACC), after a review of the relevant research, concluded that there are significantly improved outcomes and reduction of chronic heart disease, when cath lab intervention occurs within 60 to 90 minutes ('Golden Hour') of the heart attack."

43. The Agency finds that cost and financial criteria have been met.

**E. REGARDING THE RELATIONSHIP OF THE PROPOSAL TO THE EXISTING HEALTH CARE SYSTEM OF THE AREA**

44. The applicant states that the Proposal "...will help Oahu's EMS system with meeting 'golden hour' response times for acute cardiac care response." The applicant states that SFMC-W is the "...State of Hawaii's second busiest Emergency Department."

45. The applicant states that the proposal will fill a gap in the health care delivery system by providing care "...for cardiac patients who experience heart attacks within the 'golden hour' around St. Francis Medical Center-West (SFMC-W)". The applicant states that neighborhoods within the golden hour of SFMC-W are Waipahu, Ewa, Waianae Coast, Mililani/Waipio, Wahiawa, North Shore, Makakilo/Kapolei, Mililani Mauka and a portion of Koolauloa.

46. The applicant states that "Given the existing solid utilization rates at all cardiac catheterization labs that do both diagnostic and invasive procedures, this project is expected to have a minimal impact on other providers."

47. The applicant states that it will coordinate its services with other tertiary services offered at St. Francis Medical Center-West (SFMC-W), the Oahu-wide EMS system and St. Francis Medical Center-Liliha.

48. In her memorandum dated May 21, 2003, Winifred Odo, Chair, Certificate of Need Review Panel states in pertinent part: "The proposal will improve the existing healthcare system by supplying 'golden hour' interventional cardiac cath service to a large population of Oahu which was not previously available. The proposal will not adversely affect existing providers."

49. The Agency finds that this criterion has been met.

**F. REGARDING THE AVAILABILITY OF RESOURCES**

50. The applicant states that the required capital resources of \$1,800,000 for the Proposal are available through a loan with DVI, Inc. (\$1,450,000) with the remainder coming from the cash contributions of National Medical Development, SFMC-W, Cardiovascular Associates and Island Cardiac Centers.

51. The applicant states that initial operating expenses are available by a line of credit established through Cardiovascular Associates L.L.C.

52. The applicant states that its proposal will require the following patient care staffing: Registered Nurses (1.5 FTE), Cardiovascular tech (1.5 FTE) and Radiological tech (1.5 FTE). The applicant states that "its sister cardiac cath lab to



this project, Island Cardiac Centers at SFMC-Liliha, will provide start-up staffing, on call response and training of initial staff for the start up. Initial management of this cath lab will also come from the Liliha cath lab."

53. The Agency finds that the applicant has met this criterion.

### III

#### CONCLUSIONS OF LAW

Having taken into consideration all of the records pertaining to Certificate of Need Application No. 03-02 on file with the Agency, including the written and oral testimony and exhibits submitted by the applicant and other affected persons, the recommendations of the Oahuwide Certificate of Need Review Committee and the Certificate of Need Review Panel, and the Statewide Health Coordinating Council and based upon the findings of fact contained herein, the Agency concludes as follows:

The applicant has met the requisite burden of proof and has shown by a preponderance of the evidence that the Proposal meets the criteria established in Section 11-186-15, HAR.

Accordingly, the Agency hereby determines that, pursuant to Chapter 323D-43(b):

- (1) There is a public need for this proposal; and
- (2) The cost of the proposal will not be unreasonable in light of the benefits it will provide and its impact on health care costs.

#### ORDER

Pursuant to the findings of fact and conclusions of law contained herein, IT IS HEREBY DECIDED AND ORDERED THAT:

The State Health Planning and Development Agency hereby APPROVES and ISSUES a certificate of need to Island Cardiac Centers-West, L.L.C. for the proposal described in Certificate Application No. 03-02. The maximum capital expenditure allowed under this approval is \$1,800,000.

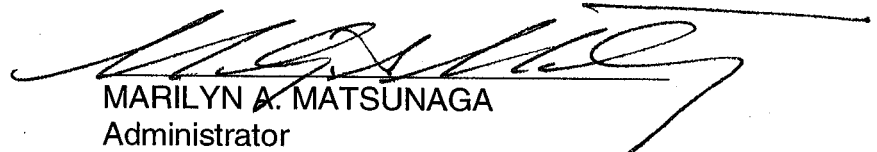
WRITTEN NOTICE

Please read carefully the written notice below. It contains material that may affect the Decision on the Merits. The written notice is required by Section 11-186-70 of the Agency's Certificate of Need Program rules.

The decision on the merits is not a final decision of the Agency when it is filed. Any person may request a public hearing for reconsideration of the decision pursuant to Section 11-186-82 of the Agency's Certificate of Need Program rules. The decision shall become final if no person makes a timely request for a public hearing for reconsideration of the decision. If there is a timely request for a public hearing for reconsideration of the decision and after the Agency's final action on the reconsideration, the decision shall become final.

DATED: June 19, 2003  
Honolulu, Hawaii

HAWAII STATE HEALTH PLANNING  
AND DEVELOPMENT AGENCY



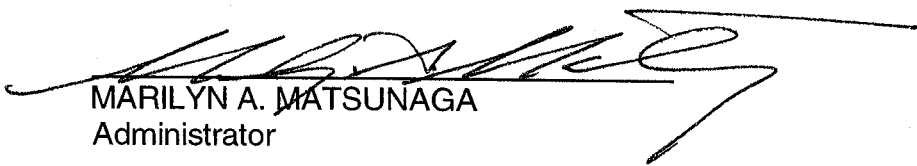
MARILYN A. MATSUNAGA  
Administrator

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the attached Decision on the Merits, including findings of fact, conclusions of law, order, and written notice, was duly served upon the applicant by sending it by certified mail, return receipt requested, in the United States Postal Service addressed as follows on June 19, 2003.

Raleigh Awaya  
Manager  
Island Cardiac Centers-West, L.L.C.  
c/o St. Francis Medical Center  
2230 Liliha Street  
Honolulu, HI 96817

HAWAII STATE HEALTH PLANNING  
AND DEVELOPMENT AGENCY

  
MARILYN A. MATSUNAGA  
Administrator